DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94360d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER
NWE-02-04W

VIA FEDERAL EXPRESS

October 8, 2003

John Andrew Roque
President and Co-Owner
Newport Fish Co.
1079 Aquidneck Avenue
Middletown, RI 02842

Dear Mr. Roque:

We inspected your seafood processing facility, Newport Fish Co., located at 1079 Aquidneck Avenue, Middletown RI, on September 17 and 18, 2003. During that investigation, our investigators documented serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your seafood products (vacuum packed smoked seafood products) are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious deviations observed were as follows:

- You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving or storage critical control points (CCP's) to control the C. botulinum hazard listed in your HACCP plan for smoked seafoods. For example, your firm receives refrigerated vacuum packed smoked seafood and does not record the temperature of the product, upon receipt, as called for in your HACCP plan. Also, your firm has not been recording the storage temperatures of your cooler, as called for in your plan.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You should include in your response any documentation, such as your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

Gail T. Costello
District Director
New England District Office